UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DENIS MULLIGAN, individually and on behalf of all others similarly situated,

Plaintiff,

v.

IMPAX LABORATORIES, INC., *et al.*,

Defendants.
_____/

HAVERHILL RETIREMENT SYSTEM, individually and on behalf of all others similarly situated

Plaintiff,

v.

IMPAX LABORATORIES, INC., *et al.*,

Defendants.
_____/

No. C-13-1037 EMC

No. C-13-1566 EMC

CONSOLIDATED CASES

ORDER DENYING DEFENDANTS' MOTION TO DISMISS CLASS COMPLAINT

(Docket No. 66)

I. INTRODUCTION

Plaintiffs Boilermaker-Blacksmith National Pension Trust and Haverhill Retirement System ("Plaintiffs") have filed the instant securities class action alleging that Defendant Impax Laboratories ("Impax") and its CEO (Larry Hsu) and CFO (Arthur Koch) made false and misleading material statements. These statements pertained to Impax's response to various FDA notices and warnings regarding problems in the manufacturing and quality control processes at Impax's manufacturing facility. Specifically, Plaintiffs allege that Defendants failed to disclose the true

nature of the problems present in the facility and misrepresented the scope, nature, and efficacy of the remediation efforts made in response to the FDA warnings. Defendants have moved to dismiss on a number of grounds, including: (1) that the alleged misstatements are protected under the Private Securities Litigation Reform Act's ("PSLRA") safe harbor provision for forward looking statements, (2) that they constitute "mere puffery," and (3) that there are insufficient allegations suggesting that the statements were false when made. Finally, Defendants argue that the Plaintiffs' allegations fail to give rise to a "strong inference" of scienter as required. The Court **DENIES** Defendants' motion to dismiss.

II. FACTUAL & PROCEDURAL BACKGROUND

Defendant Impax Laboratories is a pharmaceutical company that "engages in the development, manufacture, and marketing of bio-equivalent pharmaceutical products referred to as generics as well as branded products." First Amended Complaint ("FAC") ¶ 2. Impax maintains a manufacturing facility in Hayward, California. *Id.*

A. FDA Inspection and Noncompliance Procedures

The Food and Drug Administration ("FDA") is statutorily required to inspect all manufacturing facilities such as Impax's Hayward facility every two years, but given a lack of resources, the FDA has prioritized certain facilities over others. *Id.* ¶ 37. The purpose of these inspections is to ensure that the facility is in compliance with applicable laws and to "ensure[] the quality of drug products by carefully monitoring drug manufacturers' compliance with the FDA's Current Good Manufacturing Practice ('cGMP') regulations." *Id.* ¶ 35, 36. cGMP regulations constitute "***minimum requirements*** for the methods, facilities, and controls used in manufacturing, processing, and packaging of a drug product." *Id.* ¶ 36 (citation omitted).

Plaintiff's First Amended Complaint contains a voluminous description of the inspection process and procedures the FDA employs where a manufacturing facility is found to not be in non-compliance with cGMP. The Court need not recount the entire discussion on this point. Relevant for purposes of the instant motion, Plaintiff alleges that trained FDA "investigators tour facilities, accompanied at all times by the inspected company's staff, and cite factual observations of significant deviations from the" statutes the FDA enforces. *Id.* ¶ 42. These deviations are recorded

in a "Form 483" which is presented and explained to the company's management. *Id.* A Form 483 is intended for use in "notifying the inspected establishment's top management in writing of ***significant objectionable conditions***, relating to products and/or processes" observed during the inspection. *Id.* ¶ 44 (citation omitted). While the investigators may note whether an observation is recurring/not-corrected, it need not do so. *Id.* Investigators then draft an Establishment Inspection Report ("EIR") which contains more detail than a Form 483 and may contain additional objectionable conditions in the manufacturing facility than those listed in the Form 483. *Id.* ¶ 43. Management of a company that receives a Form 483 has an opportunity to provide written responses to the FDA. *Id.* ¶ 46. If the FDA finds a company's responses to a Form 483 to be inadequate, it may issue a Warning Letter. *Id.*

Plaintiffs provide the following definition of a "Warning Letter" (emphases in original):

> A Warning Letter is a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. ***Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected***. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.

Id. ¶ 47 (quoting FDA, *Regulatory Procedures Manual* 4.1 (2012)). Prior to issuing a Warning Letter, the FDA considers: (1) The company's compliance history; (2) the nature of the violation at issue; and (3) the overall adequacy of the firm's corrective action. *Id.* The FDA's policy states that a Warning Letter "should not be issued if the agency concludes that a firm's corrective actions are adequate and that the violations that would have supported the letter have been corrected." *Id.* (citation omitted).

B. FDA Inspections, Form 483s, and Warning Letter Regarding Impax's Hayward Facility

1. 2009, 2010, and 2011 FDA Inspections and Form 483s

In 2009, two FDA inspectors inspected Impax's Hayward facility between July 27 and August 7, 2009. *Id.* ¶ 55. They presented Impax's VP of Regulatory Affairs & Compliance (Mr.

Mark Shaw) a Form 483 which enumerated four categories of deficiencies, supported by observations of nine specific events. *Id.* These four categories of deficiencies were:

(1) the "quality system, for failure to investigate root causes of out of specification ('OOS') events;

(2) facilities and equipment, for failure to validate (*e.g.*, investigate and justify) standards Impax set for cleaning;

(3) laboratory systems, for failure to update weight calibration and for three instances of failure to note in data notebooks that certain retesting samples emanated from a particular sample that failed; and

(4) production systems, for failure to stop operations and investigate when product powder 'was flowing in a steady stream' outside of the plastic enclosure on a piece of equipment."

Id. The FAC alleges two specific occasions where product was erroneously packaged and Impax failed to document the root cause of these deviations were contained in the 2009 Form 493 – "failure to document the probable root cause for product erroneously packaged without desiccant on two occasions or to document the probable root cause related to that deviation's impact on product quality." *Id.* ¶ 52(a) (emphasis omitted)

Between April 7, 2010 and April 22, 2010, three different FDA inspectors toured Impax's Hayward facility. *Id.* ¶ 57. These inspectors again provided Mr. Shaw a Form 483 for "[s]ignificant cGMP deficiencies." *Id.* This Form 483 "contained *seven* Observations covering nine events related to manufacturing standards and review of manufacturing." *Id.* The deficiencies were generally grouped into three categories:

(1) Standard operating procedures for "scientifically unsupported cleaning procedures and deficiencies in completeness;

(2) test methods, for failure to establish the sensitivity and accuracy of QC testing methods; and

(3) lack of review of deviations with regard to metal contamination in product."

Id. The FAC specifically alleges the Form 483 called out Impax's "'failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed' and a failure to address the root cause in the investigation of metal contamination." *Id.* ¶ 52(b); 58.

Six months after receiving the April 2010 Form 483, Arthur Koch – Impax's Chief Financial Officer at the time – participated in a Goldman Sachs Healthcare Conference. When asked about the Form 483s Impax had received from the FDA, Mr. Koch replied that Impax had "gotten a small number of minor 483s that [Impax] addressed promptly." *Id.* ¶ 59. He also noted that they had perceived an increased level of scrutiny by the FDA, and that there was a clear focus on quality by the FDA. *Id.* ¶ 60. He told the participants that Impax had been able to "enjoy a very good FDA inspection record," notwithstanding the Form 483s. *Id.*

On January 21, 2011, Impax received a third Form 483 following a two month inspection. *Id.* ¶ 61. The 2011 Form 483 identified five observations relating to deficiencies in the manufacturing process or the auditing of the manufacturing process. *Id.* ¶ 62. These were:

(1) the failure to review "any unexplained discrepancy" – which was marked as a "repeat" observation by the FDA;

(2) the lack of control procedures to "validate the performance of manufacturing processes" thus "potentially causing variability of in-process material";

(3) the failure to maintain the equipment "in a manner that would prevent malfunctions and contamination";

(4) the "failure to follow and concurrently document process control procedures"; and

(5) the "failure to establish written procedures."

Id. In addition, during the 2011 inspection, an FDA investigator gave Impax's management a "verbal warning" for misleading the inspection team. *Id.* ¶ 85. Plaintiff alleges that Impax's Director of Technical Services misled an investigator by "referring several times to the metal contamination in Oxymorphone HCL extended-release as 'grey particulates" and continued to do so until shown documentation showing the "particulates" were, in fact, metal. *Id.*

In explaining the "Repeat Observation" – that Impax had failed to thoroughly review any unexplained discrepancy – the Form 483 pointed to a number of issues. First, it noted that there was

continued metal contamination in the product – an issue that had been highlighted for Impax in the 2010 Form 483. *Id.* ¶ 66. In fact, Impax had initiated and closed four "Corrective And Preventative Actions" ("CAPAs") to correct this issue, apparently without success. Second, the Form 483 faulted Impax for failing to properly investigate low-weight capsules in two batches of Impax's Fenofibrate products. *Id.* ¶ 67. Additional failures to investigate discrepancies included the failure to identify the cause of a pungent vinegar-like odor in one of Impax's products, the presence of black specs in another (and the failure of Impax to replace equipment causing the specks), and the use of powder ingredient instead of granular ingredient as required by one product's specifications. *Id.* ¶ 65. Both the Form 483 and subsequent EIR noted that these deficiencies were a violation of 21 C.F.R. § 211.192 which requires unexplained discrepancies to be thoroughly investigated. *Id.*

The remaining observations generally faulted Impax's quality control. For instance, the EIR explained that Impax employees were using pre-filled "batch records" instead of contemporaneously filling in batch records during the manufacturing process. *Id.* ¶ 69. The FDA inspectors expressed a belief that technicians were doing this to "save time" and thus were not providing a real-time record that could then be used in the investigation and resolving of any deviations in finished product that might result. *Id.* ¶¶ 69, 70. Further, the Form 483 and EIR noted inadequate and perfunctory investigations into potential discrepancies. *Id.* ¶¶ 73-74. Similarly, the FDA inspectors identified aging machines which were warped, had chipping paint (which created the risk of paint getting in pills), and frequent lubrication leaks. *Id.* ¶¶ 75-82. Plaintiff alleges that a number of Impax technicians – now serving as confidential witnesses for Plaintiff – attempted to tell Impax officials about the need for new equipment, but were ignored. *See id.* ¶ 75-84.

2. FDA Issues a Warning Letter to Impax and Impax's Public Response

Impax subsequently received a Warning Letter from the FDA. The Warning Letter stated that the FDA had reviewed Impax's response to the 2011 Form 483 and found that it "lacks sufficient corrective actions." *Id.* The Warning Letter specifically called out Impax's lack of written procedures to "monitor and validate" the manufacturing processes that could have been responsible for variations in finished products. It further noted the "Repeat Observation" from the

2010 and 2011 Form 483s regarding the failure to thoroughly investigate batches not meeting specifications (for example, through metal contamination). *Id.* ¶ 87.

On June 6, 2011, Impax released a press release announcing receipt of the Warning Letter. *Id.* ¶ 86. This press release included a quote from Larry Hsu – CEO of Impax – which stated:

> "Impax remains committed to providing the highest quality products to our customers and working with the FDA to diligently resolve any issues. . . . We intend to promptly respond to the FDA's letter, and have already begun to implement changes and establish procedures that address the observations cited during hte inspection. We will work diligently to remedy and outstanding issues in a timely manner. . . . We don't anticipate that this manufacturing setback will delay our ongoing research and development activities. We expect to continue to develop our generic pipeline of 82 products and two brand products."

Id. ¶ 154 (emphases omitted). Plaintiff alleges that during this time, analysts "responded cautiously but optimistically" to the press release, with one analyst report stating that the Warning Letter would likely cause a "temporary halt to approval of pending ANDA [Abbreviated New Drug Application] applications from the Hayward facility" and that the issues in the Warning Letter "appear fixable, and should have no long term negative impact" on Impax. *Id.* ¶ 88 (emphases omitted).

In an earnings call on August 2, 2011, Mr. Hsu allegedly informed investors that remedial measures implemented in response to the Warning Letter were nearing completion. *Id.* ¶ 156. He stated: "Many commitments in our responses are nearing completion as a result of our work since we received the Form 4[8]3. . . . We hope to be able to close out the warning letter in the next six to eight months." *Id.* (emphases omitted). On the same day, Impax released a press release regarding its Q2 2011 financial results. This press release stated, in part:

> In late June 2011, we submitted our warning letter response and will continue to cooperate with the FDA to resolve the observations. We have already made significant manufacturing and quality control systems improvements and believe we have addressed a number of the FDA's observations.

Id. ¶ 158 (emphases omitted). Two days later, Mr. Hsu and Mr. Koch signed Impax's SEC Form 10-Q for Q2 2011. Like the prior press release, this quarterly report stated, in part:

> We have taken a number of steps to thoroughly review our quality control and manufacturing systems and standards and are working with several third-party experts to assist us with our review. . . . [W]e

> have made significant quality improvements and are working to complete the material elements of our internal work as quickly as possible.

Id. ¶ 160 (emphases omitted).

Three months later in November 2011, Impax officials continued to make similar statements. In a November 1, 2011 earnings call, Mr. Koch, referring to the clearing of the Warning Letter, stated "where we are now is on track, and, therefore, I think investors can be comfortable that we're where we need to be" and then stated that they expected to hit a deadline of February 2012 for clearing the warning letter. *Id.* ¶ 162. Two days later, the Form 10-Q for Q3 2011 was released and stated, in part:

> We have made significant quality improvements and are working to complete the material elements of our efforts as quickly as possible with the goal of being able to close out the warning letter by the end of February 2012. . . . [W]e cannot assure the FDA will be satisfied with our responses and corrective actions and/or will not identify additional observations upon their re-inspection. Unless and until our corrective action is completed to the FDA's satisfaction, it is possible we may be subject to additional regulatory action by the FDA as a result of the current or future FDA observations . . . .

Id. ¶ 164 (emphases omitted). Similarly, at a Health Care Conference on November 11, 2011, Mr. Koch stated a belief that the warning letter would be closed out "before March 1, 2012, in time to preserve our first-to-file exclusivity on Trilipix, our next pipeline product." *Id.* ¶ 166.

As a result of these assurances from Impax officials, analysts issued reports which stated that management was "optimistic about [the] potential resolution" of the FDA Warning Letter and that analysts were "encouraged by m[anagement]'s focus in resolving the FDA Warning Letter." *Id.* ¶ 89. Finally, during an earnings call on February 28, 2012, Mr. Hsu stated "we have done everything we can including the mock inspections and everything. So we're pretty confident at this point we will be able to handle this FDA inspection smoothly." *Id.* ¶ 168 (emphases omitted).

During these months following the issuance of the Warning Letter, Impax officials and the FDA were in frequent contact. Plaintiff alleges that on June 27, 2011, August 5, 2011, and September 9, 2011, Impax officials wrote letters to the FDA providing "lengthy detail of the remedial measures that Impax intended to implement" as well as proposing updated standard operating procedures for metal detection. *Id.* ¶ 90. Notwithstanding these letters, the FDA sent

Impax a letter on October 4, 2011 requesting "additional details" and "clarification." *Id.* ¶ 91. The FDA's letter stated that it "remain[ed] concern[ed] with the corrective and preventative actions to the metal contamination in [Impax's] drug products" as Impax was apparently "continu[ing] to rely on surface inspection" in the new standard operating procedures. *Id.* Accordingly, the FDA reminded Impax that "surface inspection by itself is not a satisfactory method to confirm or dismiss metal contamination." *Id.* Finally, it noted that Impax had still failed to identify the root cause or causes of the underlying metal contamination. *Id.*

Impax responded with a number of letters detailing additional Corrective And Preventative Actions taken and ultimately, on January 18, 2012, informed the FDA that it had completed its response to the May 2011 Warning Letter. *Id.* ¶ 92.

3. 2012 FDA Inspection and Form 483

In early 2012, Impax brought in a third-party consulting firm – TEVA – to audit its Hayward manufacturing facility. *Id.* ¶ 94. Notwithstanding this fact, Impax received its fourth Form 483 on March 28, 2012. *Id.* ¶ 93. This Form 483 identified five general observations, supported by three separate examples. *Id.* Three of the observations related to the QC Laboratory: (1) drug products not being rejected when they failed to meet established standards; (2) investigations into the failure of a particular batch of product did not extend into other batches of the same products; and (3) standard operating procedures for testing and sampling were not followed. *Id.*

Observations 4 and 5 related directly to manufacturing processes. Observation 4 noted that Impax had failed to follow written production and process control procedures. *Id.* ¶ 94. For example, investigators noted that equipment which had been improperly stored in a manufacturing room was then used in production and sometimes contained an unidentified residue. *Id.* Further, they noted that equipment failures requiring non-routine maintenance were not consistently investigated. *Id.* Observation 5 involved a "failure to document and investigate discrepancies that arise during the course of manufacturing and QC analytical testing." *Id.* ¶ 95. Examples included "unexpected manufacturing discrepancies, including but not limited to critical equipment failures." *Id.*

Impax responded to the 2012 Form 483 in public by stressing that the issues involved were independent from those which had led to the Warning Letter. *Id.* ¶ 97. For example, during a May 1, 2012 earnings call, Mr. Hsu called the 2012 Form 483 a "temporary roadblock" and stated that the FDA's reinspection relating to the May 2011 warning letter had been conducted and they were "not aware of any outstanding issue left on that." *Id.* ¶ 170. Similarly, at a healthcare conference in June 2012, Mr. Koch stated: "It's important to understand, there were no repeat observations, so that's a way to be satisfied that the items included under the original warning letter are resolved to the satisfaction of the agency." *Id.* ¶ 174. He further noted that the issues in the 2012 Form 483 were only in the QC Lab and that the FDA "only get to that spot if they're satisfied with what's going on in manufacturing." *Id.* Finally, in September 2012, Mr. Hsu stated: "When the inspection – the re-inspection occurred in February and March, the inspector looked at the manufacturing areas, and there was no question no outstanding issue at all. They were pretty happy with what they have seen." *Id.* ¶ 176 (emphases omitted).

4. 2013 FDA Inspection and Form 483

On March 4, 2013, Impax announced that the FDA had conducted a re-inspection based on the 2011 Warning Letter as well as a general GMP inspection and had received a fifth Form 483. *Id.* ¶ 180. This most recent 2013 Form 483 included twelve observations – three of which were labeled as "repeat observations" from the 2011 Form 483 (i.e., observations of issues that existed before the Warning Letter). *Id.* That day, during a conference call with investors, Mr. Hsu stated that the "FDA standard is . . . much higher today versus a few years ago" and that "everyone knows to fix the quality it takes time." *Id.* ¶ 182. He also stated:

> "So I think from that point of view, we now learned the lesson that this is no longer [sic] internal program. We're going to have to really work with the FDA, keep them posted on the progress and we're going to have to get there [sic] as many consultants as we can to help on this whole thing which we are doing now, okay? And so, my thinking is that it does have the increased urgency significantly on this internal program."

Id. Analysts reacted negatively to the 2013 Form 483, asserting during the conference call that it "almost seems like [Impax] keep[s] studying for the wrong exam" and that the new Form 483 was "obviously very indicative of some systematic issue." *Id.* ¶ 183. Another analyst noted:

> "I think there is a disconnect between what you all are doing and what our expectations are. We would've expected you were putting maximal effort that, the program was going as fast as possible, that you would have hired as many consultants as you possibly would have needed. So it seems from an outsider these things don't make a ton of sense why you keep on getting a lot of questions around it."

Id. The market also responded drastically, with Impax common stock going from $20 per share to $14.80 per share – causing Impax to lose 26% of its market capitalization. *Id.* ¶ 184.

Plaintiff alleges that Impax officials issued statements in 2013 that were wholly inconsistent with their prior statements from 2011 that the Warning Letter would only take twelve to eighteen months to clear. For example, during a March 6, 2013 presentation, Mr. Hsu stated that "one of the important thing[s] we learned in the last two years is quality improvement is a continuing process. It's not something you can put a lot of money and resources and get it done in one year, and then say we're done with the business." *Id.* ¶ 185 (emphasis added). Similarly, during a May 2013 conference call, he stated that "it takes time, the [quality improvement program] can take two, three years to get implement[ed] on those [changes], okay." *Id.* ¶ 186.

C. Impax's Alleged Awareness of Pervasive Manufacturing and QC Deficiencies

Plaintiffs allege that Impax knew that the Hayward facility had pervasive manufacturing and QC deficiencies, such that it had no reasonable basis to assure investors that it could clear the FDA Warning Letter in a timely manner. The basis of these allegations depend primarily on confidential witnesses who were allegedly employed by Impax during the relevant period.

According to Confidential Witness 1 – a Manufacturing Technician II with Impax from 2006 through 2013 – Impax would frequently make temporary, "band aid" changes to their processes but quickly revert to their original practice once the FDA inspection ended. For example, this CW recalled that sometime after the 2011 Warning Letter, the FDA instructed Impax to place various ingredients involved in separate phases of production in separate rooms to avoid cross contamination. *Id.* ¶ 102. Impax did this, but one week after the FDA investigators left, all the ingredients were returned to their original location in the warehouse, re-exposing them to potential cross-contamination. *Id.* Similarly, Confidential Witness 5 – a Senior Manufacturing Supervisor from 2002 through 2012 – noted that when Impax knew the FDA was inspecting the facility, they

would stop production of certain products to minimize the production of dust and hide from the FDA that they had inadequate dust collection procedures. *Id.* ¶ 103. Similarly, Confidential Witness 11 – a Warehouse Supervisor from 2009 through 2013 – states that in the weeks prior to the 2012 and 2013 FDA inspections, he was ordered to move equipment and supplies from the manufacturing facility and "hide" them in a dirty, not-secure warehouse that the FDA did not know about. *Id.* ¶ 105-06. After the FDA inspection was finished, he would be ordered to return the equipment from the warehouse to the manufacturing facility. *Id.* ¶ 107.

Plaintiffs further allege that other confidential witnesses have attested to the fact that sanitation and cleanliness were frequently a problem at the Hayward manufacturing facility. For example, Confidential Witness 12 – a Manufacturing Technician and Tooling Specialist from 2006 through 2012 – states that on a number of occasions when a panel came off a machine – exposing the machine and product to contamination – he was ordered to keep the machine running instead of shutting it down for sterilization as required. *Id.* ¶ 110. Confidential Witness 5 states that during town hall meetings with executive members, manufacturing technicians complained about the lack of appropriate cleaning equipment and insufficient cleaning areas. *Id.* ¶ 113. Other employees found insects in the main manufacturing facility. The company's procedures require production to stop processing batches if insects were found, but shift managers would instruct the technicians to just 'keep going." *Id.* ¶ 114.

Plaintiffs and their confidential witnesses also assert that Impax officials were primarily concerned with wrapping up paperwork and closing investigations, rather than actually fixing problems. *Id.* ¶ 116. For example, Confidential Witness 2 – a Supervisor at the Hayward manufacturing facility from 2002 through April 2011 – reported that a Manufacturing Compliance Manager was "more concerned about the timeline" of paperwork completion than "determining the true cause of a problem." *Id.* ¶ 116. Further, other confidential witnesses reported haphazard or incomplete record keeping. Confidential Witness 4 – a manufacturing technician from February 2011 through January 2012 – noted that when there was an error on product batch records, the manufacturing technicians would simply write "entry error" on any batch record amended rather than determining what actually caused the error. *Id.* ¶ 118. Similarly, Confidential Witness 7 – a

Quality Assurance Investigation Consultant employed by the Validant consulting firm – reports that Impax recorded data in a convoluted way, preventing him from resolving a number of investigations due to gaps in data. *Id.* ¶ 123. He was further discouraged from initiating Corrective and Preventative Actions ("CAPAs") to establish new training and practices in this area. *Id.*

The FAC alleges that technicians routinely violated standard operating procedures. Confidential Witness 4 asserts that on a number of occasions, the technicians left machines unsupervised during production. *Id.* ¶ 129. Further, this witness alleges that more senior technicians would disregard standard operating procedures – and order more junior technicians to do the same – in favor of their own personal habits or procedures they felt were superior. *Id.* ¶ 130. By way of example, Confidential Witness 4 reported that technicians would clean a machine by simply rinsing it with plain water despite the fact that operating procedures required it to be rinsed with distilled water, soap scrubbed, and then rinsed a second time. *Id.* In addition, Confidential Witness 10 – a former Associate Director of HR – had to take disciplinary action against manufacturing technicians who used barrels of obsolete materials in the production process. *Id.* ¶ 132. To demonstrate that there was an awareness and tacit tolerance of standard operating procedures being violated, Plaintiffs allege that at a meeting following issuance of the Warning Letter, various technicians complaint about how the standard operating procedures slowed production. *Id.* ¶ 135. A supervisor responded by saying "That is the way you're supposed to do it. If you think you can do it better, then so be it" before adding that "if you get caught doing it the wrong way, you'll get in trouble." *Id.*

Plaintiffs also allege that Impax's facilities were simply unequipped to handle GMP regulations and could not adopt wholesale QC improvements given the limitations in the facilities, equipment, space, and technology. During a town hall meeting shortly after the 2011 Warning Letter, Mr. Hsu purportedly stated that "the way [Impax] [was] doing business was fine back in the day, but the FDA became more sophisticated" and acknowledged that Impax needed to change. *Id.* ¶ 145. According to Plaintiffs' Confidential Witnesses, however, the publicly announced goal of clearing the Warning Letter by February 2012 was "not realistic" and that it was unlikely that Impax would pass an FDA inspection given the scope of the problems at the manufacturing facility and the

nature of the equipment. *Id.* ¶ 146. The facilities and equipment at Impax's Hayward facility are alleged to have been significantly out-dated with little to no automation. *Id.* ¶ 147. Similarly, none of its lab data or notebooks were kept digitally. *Id.* ¶ 148.

Plaintiffs ultimately allege that senior management either had knowledge, or recklessly disregarded evidence of, the above issues. They support this allegation by reference to the multiple levels of review of manufacturing batch records. For instance, Confidential Witness 6 notes that when a batch was under investigation, the entire batch was held for 20-25 days during which the product did not leave the plant. *Id.* ¶ 151. This would, allegedly, cause the supply staff to become "stressed." *Id.* As a result, Plaintiffs allege that "even if executives attempted to ignore QC gaps, they nonetheless would inevitably become aware of the pervasive QC shortfalls by virtue of their investment in releasing product for distribution to meet sales goals." *Id.* Confidential Witness 6 specifically alleges that "I know for a fact that if we happened to get a deviation with a product, Jeff [Blumenfeld– Senior Director of Manufacturing–] would be called over to the building where exec[utive]s are and have a meeting. There were instances where Jeff was called over to Larry [Hsu] to discuss what was going on with this or that product." *Id.* This witness further alleges that Mr. Blumenfeld "regularly met in person on a weekly basis with Defendant Hsu, while Blumenfeld and Hildenbrand (VP of Operations) met even more frequently." *Id.* ¶ 151.

In summary, Plaintiffs allege that over the span of three years, from 2009 through 2012, the FDA repeatedly warned Defendants of their deficient manufacturing conditions, failure to properly document and investigate discrepancies, and failure to properly conduct quality control procedures. Despite these warnings, Plaintiffs allege – through a number of confidential witnesses – that Defendants either failed to undertake any action to address these concerns or applied temporary fixes or otherwise sought to hide issues from the FDA (for example, by hiding material, machinery, and the like). At the same time, however, Defendants are alleged to have made repeated statements trumpeting the remediation efforts they had employed to address the FDA's concerns.

III. DISCUSSION

Under Federal Rule of Civil Procedure 12(b)(6), a party may move to dismiss based on the failure to state a claim upon which relief may be granted. *See* Fed. R. Civ. P. 12(b)(6). While "a

complaint need not contain detailed factual allegations . . . it must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir.2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than sheer possibility that a defendant acted unlawfully." *Iqbal*, 129 S.Ct. at 1949.

Plaintiffs allege two causes of action. First, they argue that Defendants violated Section 10(b) of the Securities Exchange Act by disseminating false statements regarding Impax's ability to respond to the FDA Warning Letter. *See* 15 U.S.C. § 78j(b) (prohibiting "manipulative or deceptive" devices or contrivances in connection with the purchase or sale of securities). Second, they assert a cause of action alleging a violation of Section 20(a) of the Securities Exchange Act. *See id.* § 78t(a) (imposing joint and several liability on any individual who "directly or indirectly" controls any person liable for a violation of the Exchange Act).

Where, as here, the plaintiffs assert a claim for securities fraud pursuant to § 10(b) and Rule 10b–5, the plaintiffs must allege: "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1014 (9th Cir.2005) (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005)). To allege a claim pursuant to § 20(a), the plaintiffs must allege: "(1) a primary violation of federal securities law, and (2) that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys.*, 228 F.3d 1057, 1065 (9th Cir.2000). Here, the primary violation claimed is a violation of § 10(b) and Rule 10b–5. If Plaintiffs fail to plead a claim for securities fraud under § 10(b) and Rule 10b–5, the § 20(a) claim fails as well.

To assert a § 10(b) and Rule 10b–5 claim, the plaintiffs must meet the particularity requirements of Federal Rule of Civil Procedure 9(b). *In re Daou Sys.*, 411 F.3d at 1014. Rule 9(b) states that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake

shall be stated with particularity." The pleading requirement is further heightened by the Private Securities Litigation Reform Act ("PSLRA"), which requires that a plaintiff "plead with particularity both falsity and scienter." *Id.* To properly plead falsity, a securities fraud complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and if an allegation regarding the statement or omission is made on information and belief, state with particularity all facts on which that belief is formed." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990–91 (9th Cir.2009) (citation omitted). Likewise, to properly plead scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* at 991 (quoting 15 U.S.C. § 78u–4(b)(2) (2006)). In determining whether there is a "strong inference," the court must find sufficient allegations of scienter such that "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007)). Thus, the court must consider the complaint in its entirety and "compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Id.*

A. Plaintiffs Have Adequately Alleged a False Statement of Material Fact

The FAC alleges that the following statements made by Defendants are false or misleading statements of material fact:

- **June 6, 2011 Press Release:** "Impax remains committed to providing the highest quality products to our customers and working with the FDA to diligently resolve any issues. . . . We intend to promptly respond to the FDA's letter, and have already begun to implement changes and establish procedures that address the observations cited during the inspection. We will work diligently to remedy any outstanding issues in a timely manner . . . . We don't anticipate that this manufacturing setback will delay our ongoing research and development activities. We expect to continue to develop our generic pipeline of 82 products and two brand products." FAC ¶ 154.
- **August 2, 2011 Earnings Call, Mr. Hsu Statement:** "Many commitments in our responses are nearing completion as a result of our work since we received the Form 4[8]3.... We hope to be able to close out the warning letter in the next six to eight months." FAC ¶ 156.

- **August 2, 2011 Press Release:** "We have already made significant manufacturing and quality control systems improvements and believe we have addressed a number of the FDA's observations." FAC ¶ 158.

- **2011 Q2 10-Q Report**: "We have taken a number of steps to thoroughly review our quality control and manufacturing systems and standards and are working with several third-party experts to assist us with our review . . . . [W]e have made significant quality improvements and are working to complete the material elements of our internal work as quickly as possible." FAC ¶ 160.

- **November 1, 2011 Earnings Call, Mr. Koch Statement**: "[W]here we are now is on track, and, therefore, I think investors can be comfortable that we're where we need to be and we expect to hit that target [of the February 2012 deadline]." FAC ¶ 162.

- **2011 Q3 10-Q Report:** "We have made significant quality improvements and are working to complete the material elements of our efforts as quickly as possible with the goal of being able to close out the warning letter by the end of February 2012. However, FDA re-inspection is required to close out the warning letter, the timing of the re-inspection is wholly dependent upon FDA's availability, and we cannot assure the FDA will be satisfied with our responses and corrective actions and/or will not identify additional observations upon their re-inspection. Unless and until our corrective action is completed to the FDA's satisfaction, it is possible we may be subject to additional regulatory action by the FDA as a result of the current or future FDA observations . . . ." FAC ¶ 164.

- **November 11, 2011, Mr. Hsu Statement:** "With so much of our future and our value in our pipelines, we cannot tolerate meaningful deviations from cGMP such as those outlined in the letter. We have made a commitment to quality that is evidenced in many ways beyond our response to the FDA's letter, including we have begun to upgrade our management and our systems so that future inspections as well as the necessary re-inspection go well. The agency frequently cites that a firm's quality standards emanate from the top and we have developed a very simple clear message. We will comply, we will stay abreast of developments in our industry and we will remain compliant as we build our business. The tasks necessary to address the three issues raised in the letter are well underway and an even greater effort to upgrade our global quality system was initiated at the direction of our new leadership in both quality and manufacturing . . . . [w]e believe we can close out the warning letter before March 1, 2012, in time to preserve our first-to-file exclusivity on Trilipix, our next pipeline product. Of course this estimate depends heavily on the timing of the FDA's review. . . ." FAC ¶ 166.

- **February 28, 2012 Earnings Call, Mr. Hsu Statement:** "As we pointed out in the past that we cannot adjust on the timing [on a reinspection from the FDA], but from our end we have done everything we can including the mock inspections and everything. So we're pretty confident at this point we will be able to handle this FDA inspection smoothly." FAC ¶ 168.

- **May 1, 2012 Earnings Call, Mr. Hsu Statement:** "Even though the recent FDA inspection had no repeat deficiencies or observations from those cited in the 2011 warning letter, we are disappointed to have a new [F]orm 483 related to our quality control laboratory. We have responded to the FDA on the items mentioned in this 483 and will continue to work as quickly as possible to resolve these items. . . . It remains the top priority throughout the company . . . . [W]e will continue to devote every available resource in order to achieve and maintain FDA compliance. This temporary roadblock has not prevented us from continuing to manufacture . . . . [A]t this point, [the] FDA has conducted the reinspection in connection to the [May 2011] warning letter and as of today we're not aware of any outstanding issues left on that." FAC ¶ 170.

- **May 16, 2012 Statements by Mr. Koch and Mr. Hsu:** "[W]e're very confident that we'll be able to deal with all of the issues we face and resolve this current report as quickly as possible" and "While we don't know the exact the timing on that, but [sic] we have a real confidence that we will get the issue resolved." FAC ¶ 172.

- **June 7, 2012 Statement by Mr. Koch:** "The[] [FDA] went on to do a full cGMP inspection. They went into the QC lab, that's the last stop before the product is distributed, and observed these additional items. It's important to understand, there were no repeat observations, so that's a way to be satisfied that the items included under the original warning letter are resolved to the satisfaction of the agency . . . . [The new cited violations are] in the QC lab and that is – that only – they only get to that spot if they're satisfied with what's going on in manufacturing. It's only a policy and procedures kind of comment and issue. We were able to revise the policies and procedures before the inspectors left the office. So it's a very easy thing to address. Now we [are] working with them on their remaining questions as to our current product." FAC ¶ 174.

- **September 20, 2012 Statement by Mr. Hsu:** "When the inspection – re-inspection occurred in February and March, the inspector looked at the manufacturing areas, and there was no question no outstanding issue at all. They were pretty happy with what they have seen. However, they did look at the QC lab, when the[y] look[ed] at it they found some problem[s], procedure problem[s]." FAC ¶ 176.

- **October 30, 2012 Earnings Call, Mr. Hsu Statement:** "But at this point, as I pointed out earlier, we're confident we'll get out of here, although timing, unfortunately, is not in our control, as we're waiting for [the] FDA to take the action on that. But I think we feel well prepared for this." FAC ¶ 178.

Defendants argue that the above statements are not actionable because: (1) Plaintiffs have failed to allege facts suggesting that the statements were false when made; (2) that the PSLRA's "safe harbor" provision applies, and (3) the statements are non-actionable "puffing" or statements of opinion. The Court addresses each argument in turn.

1. Plaintiffs Have Adequately Alleged that the Statements Were False When Made

Defendants argue that Plaintiffs have failed to allege that the statements contained in the FAC were actually false when they were made. Under §78u-4(b)(1), plaintiffs must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief . . . the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u(b)(1). Thus, in order to be actionable the statement in question must have been false when made. *See Feyko v. Yuhe Intern., Inc.*, No. CV 11-05511 DDP (PJWX), 2013 WL 816409, at *4 (C.D. Cal. Mar. 5, 2013). Further, "[t]o be actionable under the securities laws, an omission must be misleading; in other words it must affirmatively create an impression of a state of affairs that differs

in a material way from the one that actually exists." *Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002).

a. For Purposes of the Motion to Dismiss, Plaintiffs Have Adequately Alleged Defendants' Statements Were False When Made

As to each challenged statement, Plaintiffs allege that the statement was "materially false and misleading when made because they failed to disclose the following adverse material facts, which were known to Defendants or recklessly disregarded by them and which, if disclosed, would have rendered Defendants' statements not misleading: that Impax was not equipped to address and remedy the observations of GMP deficiencies as cited in the Warning Letter." FAC ¶ 155, 157, 159, 161, 163, 165, 167, 169, 171, 173, 175, 177, 179. Plaintiffs state that Defendants were "not equipped to address and remedy" the observations because:

- "(a) Impax had a practice and culture of implementing and reversing corrective measures as a temporary solution to pass FDA onsite inspections." *Id.* ¶ 155.
- "(b) Impax had a demonstrated history of problems with cleanliness and sanitation exacerbated by its lack of space for its operations, the failure to stop production when insects were found or as required when certain machinery malfunctioned, and technicians chronically disregarded SOPs pertinent to cleaning." *Id.*
- "(c) Impax employees did not observe proper cGMP practices regarding documentation and maintenance of adequate batch records because technicians pre-filled or wholesale completed batch records rather than doing so step-by-step, employees in the laboratory maintained a convoluted and confusion system to record raw data, and technicians or audit teams failed to fully investigate . . . deviations in production." *Id.*
- (d) Impax had antiquated machinery that was in chronic disrepair . . . ." *Id.*
- (e) "Impax had continually failed to locate all root causes of metal contamination and the 'black specks' contamination in other tablets." *Id.*
- "(f) Impax employees rampantly disregarded SOPs and trained new staff to disregard SOPs . . . ." *Id.*
- "(g) both before and after the Class Period . . . Impax repeatedly appointed or failed to remove employees who were or became unqualified or untrained for their positions." *Id.*
- "(h) both before and after the Class Period, Impax facilities were generally inadequate because they lacked sufficient space to avoid storing products incorrectly in the hallways or non-conforming warehouses, equipment was lacking or technologically insufficient to support proper cGMP practices." *Id.*

- "(I) both before and after the Class Period . . . Impax failed to fully investigate and document deviations in manufacturing." *Id.*

In light of the extensive confidential witness allegations (discussed *infra*), and taking all inferences in the light most favorable to Plaintiffs, the Court concludes that Plaintiffs have adequately alleged that the statements contained in the FAC were false or misleading when made. The FAC alleges recurring and pervasive problems with the manufacturing and quality control processes at Impax's Hayward facility – many of which were identified by the FDA on more than one occasion. Other allegations describe actions which call into question whether there was ever a true commitment to remedy the manufacturing and quality control problems. For example, Plaintiffs allege – through three separate confidential witnesses – that it was routine procedure for Defendants to implement "temporary" changes/improvements to pass an FDA inspection only to undo the change shortly after the inspection concluded. Some of these incidents are alleged to have occurred after the 2011 Warning Letter and Defendants' statements about remediation efforts being employed. *Id.* ¶¶ 102-109.

Further, the 2011 Warning Letter highlighted two issues – (1) lack of written procedures to monitor and validate manufacturing processes that could have caused product variability and (2) failure to investigate deviations in the manufacturing process. *Id.* ¶ 87. However, notwithstanding the statements in 2011 that changes and procedures had been implemented to address the observations (and, in fact, that these changes were "nearing completion"), similar observations were raised by the FDA in the 2013 Form 483. Specifically, it is alleged that the 2013 Form 483 cited Impax's "failure to thoroughly review an unexplained discrepancy and the failure of the batch or any of its components to meet . . . specifications." *Id.* ¶ 99. Thus, similar issues were subsequently found 18 months after Defendants stated that they had implemented changes to address the FDA concerns.[1]

[1] Both in their papers and at the hearing, the parties debated the significance of the FDA flagging, or not flagging, certain observations as "Repeat Observations." The FAC has alleged that FDA inspectors may, but are not required to, mark a recurring or not corrected observation as a"Repeat Observation." The Court need not resolve the significance of some observations being labeled as a "Repeat Observation" while others were not. Rather, the Court finds it sufficient for its

Of course, the fact that Defendants' remediation efforts may have ultimately been unsuccessful or insufficient does not, on its own, establish the falsity of Defendants' statement at the time they were made. *See N.Y. State Teachers' Ret. Sys. v. Fremont Gen. Corp.*, No. 2:07-cv-5756-FMC-FFMx, 2009 WL 3112574, at *10 (C.D. Cal. Sept. 25, 2009) ("[T]he fact that subsequent disclosures revealed that the remedial measures were not sufficient does not render false the individual Defendants' contemporaneous statements about those measures."). However, given the pervasive, recurring, and long-standing nature of the alleged problems identified in the FAC, the Court cannot conclude (at this stage) that Defendants' statements regarding the remediation efforts being implemented were not false or misleading when made.

Similarly, the Court finds that Plaintiffs have adequately alleged that Defendants' representations regarding the nature of the 2012 Form 483 were false or misleading. Plaintiffs generally allege that Defendants misrepresented that the FDA's concerns in the Form 483 only addressed the QC lab, and there were no issues with manufacturing. Plaintiffs have alleged that the 2012 Form 483 did, in fact, refer to manufacturing issues. Specifically, the Form 483 targeted: (1) Defendants' failure to follow "written production and process control procedures" with examples being Defendants' storing equipment in the manufacturing room and being coated in unidentified product residue and equipment failures that were not consistently investigated; and (2) "failure to document and investigate discrepancies that arise during the course of manufacturing and QC analytical testing." FAC ¶ 94-95.

The Court must view allegedly false statements "in full and in context at the time it was made." *In re Syntex Corp. Securities Litig.*, 95 F.3d 922, 929 (9th Cir. 1996). Defendants attempt to argue that in context, the Defendants were simply asserting that there were no "Repeat Observations" regarding manufacturing in the 2012 Form 483. The Court disagrees. The FAC alleges Defendants made broad statements regarding the FDA's purported approval of Impax's manufacturing processes. For example: "When the inspection – re-inspection occurred in February

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purposes of the Rule 12(b)(6) motion to note that the description of the observations from one year to another gives rise to a reasonable inference that problems were not adequately addressed or remediated.

and March, the inspector looked at the manufacturing areas, and there was no question no outstanding issue at all. They were pretty happy with what they have seen." FAC ¶ 176. This is simply not true according to the FAC – the 2012 Form 483 highlighted issues with the manufacturing process. Further, even if the statement was meant to imply there were no *recurring* manufacturing issues identified, this, too, appears inaccurate. Specifically, the 2012 Form 483 included as one of its observations the "failure to document and investigate discrepancies that arise during the course of manufacturing and QC analytical testing." *Id.* ¶ 95. As discussed above, the FDA had previously highlighted (in 2009, 2010, and 2011) Impax's failure to investigate deviations during the manufacturing process. *See id.* ¶ 87.

Accordingly, the Court concludes, for purposes of the motion to dismiss only, that Plaintiffs have alleged with sufficient particularity under the PSLRA and the plausibility standard of *Iqbal* and *Twombly* that the statements identified in the FAC were false or misleading when made.

b. The FAC Properly Alleges and Relies Upon Confidential Witnesses

In describing why Defendants' representations were false when made, Plaintiffs rely extensively on factual allegations obtained from confidential witnesses. Defendants argue that the confidential witness allegations should be disregarded as unreliable. Under Ninth Circuit law, a "confidential witness must be 'described with sufficient particularity to establish [his or her] reliability and personal knowledge'" – that is, "'with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.'" *Oclaro*, 2013 WL 2384244, at *9 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009)). In determining the reliability of confidential witnesses, the court must look at the "level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Zucco Partners*, 552 F.3d at 995. The Ninth Circuit has held that numbering the confidential witnesses and describing the witnesses' job description and responsibilities constitutes a "large degree of specificity," especially where the witnesses' exact title is used. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1016 (9th Cir. 2005).

The Court finds that the FAC has provided sufficient, particularized allegations regarding the reliability and personal knowledge of the confidential witnesses. The FAC has identified thirteen confidential witnesses who have provided consistent accounts of the conditions, practices, and procedures of Impax within their respective spheres. While the Defendants assert that Plaintiffs have only utilized "vague job titles," Plaintiffs assert they have used the actual titles used by Impax. A review of the complaint supports Plaintiffs' assertion. *See, e.g.*, FAC ¶ 22 (CW 1 described as a "Manufacturing Technician II"); *id.* ¶ 24 (listing that CW 3 occupied the positions of "Manufacturing Technician I," then served as "Production Engineering Associate," and then as "Manufacturing Engineer"); *id.* ¶ 27 (listing CW 6 as "Associate Director of Manufacturing" and "Associate Plant Manager"). In addition, the FAC states to whom each confidential witness reported. The Court finds that the description of job titles and job responsibilities have been stated with sufficient particularity. *See In re Daou*, 411 F.3d at 1016 ("Plaintiffs here describe the confidential witnesses with a large degree of specificity. Plaintiffs number each witness and describe his or her job description and responsibilities. In some instances, plaintiffs provide the witnesses' exact title and to which Daou executive the witness reported.").

Defendants also argue that 9 of the confidential witnesses – CWs 1-4, 6, 10-13 – are not alleged to have any connection to Impax's remediation efforts and therefore had "no personal knowledge as to whether or not Impax had the ability to resolve the warning letter." Mot. to Dismiss at 17-18. Defendants view the inquiry too narrowly. Plaintiffs use the confidential witnesses in an attempt to demonstrate the pervasive and systemic nature of Impax's problems and the purposefulness in failing to address and remedy these problems, from which the falsity of Defendants' statements about Impax's remedial efforts may be inferred. The question, therefore, is whether Plaintiffs have properly alleged facts suggesting that the confidential witnesses have personal knowledge about the incidents they address. The Court finds that they have. Defendants provide two examples – CW 5 and CW 8 – for which they argue Plaintiffs have provided only "vague allegations" of personal knowledge. Motion to Dismiss at 18. CW 5 is alleged to have been a "Senior Manufacturing Supervisor" who observed manufacturing technicians and "oversaw all aspects of manufacturing operations to facilitate compounding tableting, encapsulation, and

coating." FAC ¶ 26. Plaintiffs further allege that CW5 "drafted work schedules and reviewed batch records, and was charged with maintaining compliance with FDA regulations." *Id.* The FAC contains a number of specific incidents and issues that CW 5 allegedly witnessed first hand – from inadequate space, to inadequate cleaning facilities creating the risk of cross-contamination, inadequate and antiquated machinery, and the like. *Id.* ¶¶ 103, 113, 147. Similarly, CW 8 is alleged to have been a "Director of Global Training" who worked in quality assurance and "worked with contracts that Impax brought in to assist the Company with its quality improvements in response to FDA inspections." *Id.* ¶ 29. Specifically, CW 8 "was responsible for the development and management of technical and regulatory training, and integrated quality compliance systems for Impax." *Id.* The FAC alleges that CW 8 felt that there was insufficient quality assurance in the research and development department, was present in meetings with the FDA when the inspections occurred, that the problems highlighted by the FDA were "rather old" in that they had been going on for a long time, and that he felt the asserted remediation time frames were unrealistic. *Id.* ¶¶ 150, 153.

The FAC contains sufficient allegations to establish the reliability of the confidential witnesses. Accordingly, the Court properly may consider the CWs and their allegations in determining whether Plaintiffs have properly alleged the statements were false when made.

2. The PSLRA Safe Harbor Does Not Apply

Under the PSLRA, a person may not be held liable for making an untrue statement of material fact if the statement is (1) a statement that is, and is identified as, a "forward-looking statement" and (2) is accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A); *see also In re Cutera Securities Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010). Under this "safe harbor" provision, a "forward-looking statement" is defined as "any statement regarding (1) financial projection, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions 'underlying or related to' any of these issues." *Bartlet v. Affymax, Inc.*, 13-CV-01025-WHO, 2014 WL 231551, at *13 (N.D. Cal.

Jan. 21, 2014) (quoting *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 936 (9th Cir. 2003)).

Plaintiff argues that the above identified statements do not constitute "forward-looking statements" because they are misrepresentations regarding the "historical and present" facts regarding Impax's alleged manufacturing and quality control improvements. By contrast, in their motion to dismiss, Defendants point to other parts of the same comments as examples of "forward-looking" statements. *See, e.g.*, *id.* ¶ 154 ("we intend to promptly respond the FDA's letter . . . ."); *id.* ¶ 166 ("We will comply, we will stay abreast of developments in our industry."). Defendants argue that these statements are forward-looking because they represent the likelihood and timing of a future event, specifically the remediation of the issues raised in the FDA Warning Letter.

In support of their argument, Defendants cite to a number of cases where statements regarding future FDA actions were found to be forward-looking for purposes of the safe harbor. For example, in *Kovtun v. Vivus, Inc.*, No. C 10-4957 PJH, 2012 WL 4477647 (N.D. Cal. Sept. 27, 2012), plaintiffs alleged that defendant's statements regarding the prospects of a new drug were false and misleading. The court found the safe harbor applicable, stating that "[p]rojections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the company's plan for its product, and as such fall under the PSLRA's safe harbor rule." *Id.* at *12; *see also In re Nuvelo, Inc. Securities Litig.*, No. C 07-4056 VRW (N.D. Cal. Dec. 4, 2008) (finding that "alleged misstatements about the likelihood of future success at phase 3 trials, regulatory approval, or commercialization of [the drug] alfimeprase all fit the definition of forward-looking statements under the PSLRA").

The Court finds that the statements enumerated above do not fit within the PSLRA's definition of a "forward-looking" statement. These statements all contain representations of present or historical fact – for example, the assertion that Impax had "begun" to institute changes to address the issues highlighted by the FDA, or that tasks to address these issues were "well under way." The identified statement which comes the closest to fitting the definition of "forward-looking" is the November 1, 2011 statement by Mr. Koch asserting that Impax was "on track" and that investors could feel comfortable with where the company was. FAC ¶ 162. Even this statement, however, is

fundamentally a representation of present fact regarding the status of Impax's response to the FDA Warning Letter. Further, as Plaintiffs have pointed out, at least one court has found similar "on track" language to be not forward-looking. *See In re MGM Mirage Sec. Litig.*, No. 2:09-cv-01558-GMN-VCF, 2013 WL 5435832, at *7 (D. Nev. Sept. 26, 2013) ("However, statements that a project is "on-track," "on-budget," or "on-schedule," are not forward-looking but statements relating to *current* conditions.").

Defendant argues that notwithstanding the present-focus of these statements, they can constitute forward-looking statements because "[h]istorical statements can also be forward-looking if they are presented as factors underlying a projection or economic forecast." *In re LeapFrog Enters., Inc. Securities Litig.*, 527 F. Supp. 2d 1033, 1046 (N.D. Cal. 2007). The Court disagrees. In *Westley v. Oclaro, Inc.*, 897 F. Supp. 2d 902 (N.D. Cal. 2012), plaintiffs argued that defendants' statements that they were "currently seeing a return of customer demand" and that "customer demand has recently increased" were false and misleading. *Id.* at 909. Despite the focus of these statements on *current* consumer demand, defendants argued that the statements were, in fact, forward-looking because the present-fact was "being used to make predictions about the future" and thus represented a "statement or assumption" underlying a forward-looking statement. *Id.* at 918; *see also* 15 U.S.C. § 78u-5(i)(1)(D). This Court rejected defendants' argument, holding that notwithstanding the forward-looking context in which the statement was made, "[t]he fact remains that a statement about a past or current fact can demonstrably be proven false. That is what distinguished such facts from forward-looking predictions." *Oclaro*, 897 F. Supp. 2d at 918. Accordingly, the Court found the safe harbor provision inapplicable.

This Court's decision in *Oclaro* is supported by numerous cases from around the country which have held that statements of past or present *facts* are not covered by the safe harbor provision – even when they are inextricably tied with forward-looking statements. For example, in *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 513 F.3d 702 (7th Cir. 2008), the Seventh Circuit stated that when a company:

> told the world that sales of its 5500 system were 'still going strong,' it was saying both that current sales were strong and that they would continue to be so, at least for a time, since the statement would be

> misleading if Tellabs knew that its sales were about to collapse. The element of prediction in saying that sales are 'still going strong' does not entitle Tellabs to a safe harbor with regard to the statement's representation concerning current sales.

Id. at 705. Further, the Third Circuit has recognized that "'[a] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present.'" *Institutional Investors Group v. Avaya, Inc.*, 564 F. 3d 242, 255 (3d Cir. 2009) (quoting *Makor*, 513 F.3d at 705)); *see also EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865 (3d Cir. 2000) (recognizing that a statement that "lengthy negotiations" had already taken place and that contracts were "imminent" could reasonably be construed as a "representation about the current state of negotiations"). Similarly, the Southern District of New York has recognized that "[s]tatements that might arguably have some forward-looking aspect are unprotected by the PSLRA safe harbor provision to the extent that they are premised on representations of present fact." *In re Regeneron Pharm. Inc. Sec. Litig.*, No. 03 Civ. 3111 RWS, 2005 WL 225288, at *13 (S.D.N.Y. Feb. 1, 2005); *see also Sgalambo v. McKenzie*, 739 F. Supp. 2d 453, 478 (S.D.N.Y. 2010) (finding statements that "incorporate forward-looking aspects into statements of present fact" are not covered by the PSLRA safe harbor provision).

Because the Court concludes that the statements identified in the FAC on what Plaintiffs rely to state their claim are, at least in part, statements of present or historical fact and not forward-looking, the Court concludes that the PSLRA safe harbor does not apply and need not address whether Defendants' cautionary language was "meaningful." *See, e.g.*, *City of Hialeah Employees' Retirement Sys. & Laborers Pension Trust Funds v. Toll Brothers, Inc.*, No. 07-1513, 2008 WL 4058690, at *2 (E.D. Pa. Aug. 29, 2008) ("[B]ecause these statements were not forward-looking . . . the safe harbor provision of the PSLRA [is] inapplicable.").

3. The Statements Do Not Constitute Unactionable "Puffing" or Opinions

Defendants further contend that the statements in the FAC cannot constitute material falsehoods, because they constitute general statements of corporate optimism – "mere puffery." "'Vague statements of opinion are not actionable under the federal securities laws because they are considered immaterial and discounted by the market as mere puffing.'" *In re OmniVision Techs.*,

Inc. Sec. Litig., 937 F. Supp. 2d 1090, 1102 (N.D. Cal. 2013) (quoting *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1245 (N.D. Cal. 1998)). As the Ninth Circuit has noted, "[w]hen valuing corporations, . . . investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers." *In re Cutera*, 610 F.3d at 1111. Thus, courts have noted that "puffing" statements are generally "'not capable of objective verification,' and 'lack[] a standard against which a reasonable investor could expect them to be pegged.'" *In re Cornerstone Propane Partners, L.P.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005) (quoting *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1119 (10th Cir. 1997)). For example, courts have found unactionable statements asserting "[w]e are very pleased with the learning from our pilot launch" and "so far we're getting really great feedback." *City of Royal Oak Retirement Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1063 (N.D. Cal. 2012) (citing *Wozniak v. Align Tech., Inc.*, 850 F. Supp.2d 1029, 1036 (N.D. Cal. 2012)).

"When determining whether statements amounted only to puffery, the court must analyze the context in which the statements were made." *In re Bridgepoint Educ., Inc. Sec. Litig.*, No. 3:12-CV-1737 JM (WMC), 2013 WL 5206216, at *17 (S.D. Cal. Sept. 13, 2013). Even a statement of opinion or an expression of corporate optimism may be deemed actionable in certain circumstances because "there is a difference between enthusiastic statements amounting to general puffery and opinion-based statements that are anchored in 'misrepresentations of existing facts.'" *In re Bank of Am. Corp. Sec., Derivative, & ERISA Litig.*, 757 F. Supp. 2d 260, 310 (S.D.N.Y. 2010) (quoting *Novak v. Kasaks*, 216 F.3d 300, 315 (2d Cir. 2000)). As the Ninth Circuit stated in *Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989), "What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation." Accordingly, the Court may not assess the statements listed in the FAC in a vacuum, "plucking the statements out of their context to determine whether the words, taken *per se*, are sufficiently 'vague' so as to constitute puffery," but rather will examine the entire statement and its circumstances to determine if it is actionable. *Scritchfield v. Paolo*, 272 F. Supp. 2d 163, 176 (D.R.I. 2003).

As an initial matter, the Court notes that "puffery" is not-actionable under the PSLRA because the law deems such statements so amorphous as to be immaterial. *See In re Omnivision*, 937 F. Supp. 2d at 1102. However, determining whether a given statement is material "entail[s] fact-intensive assessments that are more properly left to the jury." *Bricklayers & Masons Local Union No. 5 Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223, 244 (S.D.N.Y. 2012). Thus, "[i]n deeming a statement puffery at the motion to dismiss stage, courts must exercise great caution." *Id.*; *see also In re Spiegel, Inc. Sec. Litig.*, 382 F. Supp. 2d 989, 1028 (N.D. Ill. 2004) (declining to hold that statements were puffery at the motion to dismiss stage because materiality involves "delicate assessments of the inferences a reasonable shareholder would draw"). Accordingly, this Court will only grant Defendants' motion to dismiss on the ground that the statements are "puffery" only if it concludes that the statement is "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their unimportance." *In re Ford Motor Co. Sec. Litig.*, 381 F.3d 563, 570 (6th Cir. 2004) (citation omitted); *see also In re Scientific-Atlanta, Inc. Sec. Litig.*, 239 F. Supp. 2d 1351, 1360 (N.D. Ga. 2002) ("A statement can be dismissed as puffery as a matter of law only if it is immaterial because it is so exaggerated or so vague that a reasonable investor would not rely on it in considering the 'total mix' of facts available.").

The Court finds that it cannot so conclude. To be sure, the statements include superlatives which are indicative of the speaker's opinion and are often seen in "puffing" statements – for example, references to "significant" manufacturing and quality control improvements. *See* FAC ¶¶ 158, 160. However, as the Court found above in its discussion over whether these statements are "forward-looking," the vast majority[2] of the statements identified in the FAC contain factual

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[2] The Court finds that the following statements represent either a non-actionable opinion or mere puffery:

- **May 16, 2012 Statements by Mr. Koch and Mr. Hsu:** "[W]e're very confident that we'll be able to deal with all of the issues we face and resolve this current report as quickly as possible" and "While we don't know the exact the timing on that, but [sic] we have a real confidence that we will get the issue resolved." FAC ¶ 172.
- **October 30, 2012 Earnings Call, Mr. Hsu Statement:** "But at this point, as

representations at their core – that Defendants had responded to the FDA Warning Letter by instituting various changes to the manufacturing and/or quality control procedures or processes. *See, e.g.*, FAC ¶ 154 ("We . . . *have already begun to implement changes and establish procedures* that address the observations cited during the inspection."); *id.* ¶ 156 ("Many commitments in our responses are nearing completion as a result of our work since we received the Form 4[8]3 . . . ."). Similarly, that certain statements are predicated with indications that the speaker "thought" or "believed" a given statement does not change this result. *See In re Oxford Health Plans, Inc.*, 187 F.R.D. 133, 141 (S.D.N.Y. 1999) ("It is disingenuous to suggest that factual assertions are puffery and opinion that no reasonable investor could reasonably rely on for their truth simply because Oxford claims only to have stated that it believes in their truth.").

With the two exceptions noted above in Footnote 1, the representations identified in the FAC are distinguishable from those cases that Defendants have cited in support of their puffery argument. For example, in *City of Royal Oak Retirement System v. Juniper Networks, Inc.*, the court found that statements which simply "express[ed] confidence in Juniper's business and outlook" were vague assertions of corporate optimism. *Id.* at 1064. Among such statements were representations that "[b]oth Verizon and AT&T are strong partners," that it had "strong demand metrics and good momentum," and that "growth drivers give us . . . confidence." *Id.* Similarly, in *Wozniak v. Align Tech., Inc.*, the court found that statements that "[w]e are very pleased with the learning from our pilot launch," "we're getting really great feedback," "we are very pleased with our progress to date on key strategic initiatives," were mere puffery. *Wozniak*, 850 F. Supp. 2d at 1036.

Rather, the Court finds that this case is similar to *Bricklayers and Masons Local Union No. 5 Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223 (S.D.N.Y. 2012). There, Transocean – a deepwater drilling company – represented in a merger agreement, proxy statement, and SEC Form 10-K that it had conducted "extensive" training and safety programs. *Id.* at 230. Approximately three years later, the *Deepwater Horizon* disaster occurred, raising serious questions about

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> I pointed out earlier, we're confident we'll get out of here, although timing, unfortunately, is not in our control, as we're waiting for [the] FDA to take the action on that. But I think we feel well prepared for this." FAC ¶ 178.

Transocean's management, personnel, and equipment failures. *Id.* at 228. In a subsequent securities lawsuit, plaintiffs asserted that the representation regarding Transocean engaging in "extensive" training and safety was false and misleading. The district court rejected defendant's argument that this statement constituted mere puffery: "In an industry as dangerous as deepwater drilling, it is to be expected that investors will be greatly concerned about an operator's safety and training efforts. The Court cannot say, as a matter of law, that Transocean's representation that such efforts were extensive was 'obviously unimportant'" to shareholders. *Id.* at 244; *see also In re Spiegel*, 382 F. Supp. 2d at 1028 (finding statements that preferred credit card programs realized "significant" earnings and "solid" sales and earnings were not puffery at the motion to dismiss stage).

Here, the challenged statements were allegedly made by Defendants at a time when one of their two manufacturing facilities had received significant warnings from the FDA. It is reasonable to believe that investors in the pharmaceutical industry – an industry where regulatory compliance, not to mention consistency and sanitation in production, is essential – would find such an event disconcerting. This is especially the case when the very core of Impax's business – its manufacturing facilities – was in potential jeopardy. Indeed, it is highly plausible that the investors would find statements by the company's head officers that appropriate responses were "well underway" or nearly completed to be material. This is precisely the picture painted by the statements enumerated in the FAC. Defendants are alleged to have specifically represented to investors that they had undertaken significant manufacturing and quality control changes in their operations to rectify the issues highlighted by the FDA's Form 483s and Warning Letter in a relatively short period of time. In other statements, Defendants assured investors that subsequent FDA warnings were unrelated to the prior incidents. At the same time, it is alleged that, in fact, Defendants did little in response and that similar issues continued to pervade Impax's Hayward facility. Given this context, the Court cannot find at this stage that the alleged statements are simple statements of corporate optimism or mere puffery. They were not so "obviously unimportant" to shareholders as to warrant dismissal.

B. Plaintiffs Have Sufficiently Alleged Scienter Under the Core Operations Theory

Under the PSLRA, plaintiffs must plead "with particularity facts giving rise to a *strong inference*" that the Defendants acted with scienter when making the alleged false statements. 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). In determining whether the facts give rise to a "strong" inference of scienter, "the court must take into account plausible opposing inferences." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). "A strong inference of scienter must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Reese v. Malone*, — F.3d — , 2014 WL 555911, at *6 (9th Cir. Feb. 13, 2014). The inference must be that the "'defendant[] made false or misleading statements either *intentionally* or with *deliberate recklessness*.'" *Id.* (quoting *Zucco*, 552 F.3d at 991 (emphasis in original)).

Plaintiffs do not specifically allege direct evidence showing the key officers making the statements at issue – the CEO Mr. Hsu and the CFO Mr. Koch – had knowledge of the falsity of the statements. Rather, they rely on the "core operations" theory to show such knowledge.

Under that theory, scienter may be imputed "based on the inference that key officers have knowledge of the 'core operations' of the company." *Id.* at *13. Specifically, in "rare circumstances" allegations regarding management's role "may be sufficient, without accompanying particularized allegations, where the nature of the relevant fact is of such prominence that it would be 'absurd' to suggest that management was without knowledge of the matter." *Id.*; *see also Zucco*, 552 F.3d at 1000 ("Nevertheless, reporting false information will only be indicative of scienter where the falsity is patently obvious – where the 'facts [are] prominent enough that it would be 'absurd to suggest' that top management was unaware of them.'" (quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 989 (9th Cir. 2008)).

By way of example, in *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003), plaintiffs alleged that defendants – including outside directors and shareholders of America West – made knowingly false statements regarding the company's financial outlook and response to various operational problems. Specifically, plaintiffs alleged that aircraft maintenance had "deteriorated dramatically" as a result of

outsourcing of maintenance, leading to repeated FAA investigations and warnings. *Id.* at 926. Regardless, the defendants made extremely positive statements about the company's financial outlook and asserted that maintenance and operational problems were behind the company. *Id.* at 927. The Court found that plaintiff had adequately alleged that the shareholder and director defendants were aware of the misstatements made by America West's officers and therefore had adequately alleged scienter. The Court stated, in part:

> TPG argues that the issues regarding maintenance, safety, and the FAA investigation and settlement were "purely[] management issue[s] that never rose to the level of Board discussions or communications with any shareholders." This argument is patently incredible. It is absurd to suggest that the Board of Directors would not discuss . . . the FAA investigations or negotiations, especially considering the fact that the FAA had indicated that it was considering penalties of up to $11 million.

Id. at 943 n.21.

Similarly, in *Berson v. Applied Signal Technology, Inc.*, 527 F.3d 982 (9th Cir. 2008), the plaintiffs alleged that defendants – Applied Signal's CEO and CFO – made materially false statements regarding Applied Signal's revenue by including in the company's "backlog" report various contracts for which the government had issued "stop-work orders." *Id.* at 985. This was significant because contracts for which the government had issued a "stop-work order" are often cancelled altogether, thus creating a great degree of risk that the company would never receive money for those contracts. *Id.* Thus, plaintiffs alleged that the "company's backlog reports misled them into believing that Applied Signal was likely to perform work that, in reality, had been halted and was likely to be lost forever." *Id.* The Ninth Circuit found that plaintiffs had adequately alleged scienter. The court acknowledged that "plaintiffs allege no particular facts indicating that [defendants] actually knew about the stop-work orders." *Id.* at 987. Still the court found accepted the inference that the "high-level managers must have known about the orders because of their devastating effect on the corporation's revenue." *Id.* The Court noted that the inference was even stronger than in *America West* because "[d]efendants in *America West* were outside directors who did no more for the company than attend board meetings and serve on a board committee. Here, by contrast, [defendants] were directly responsible for Applied Signal's day-to-day operations." *Id.*

This case is similar to *America West* and *Applied Signal*. As in those cases, it is "absurd" to think that the CEO and CFO of a pharmaceutical company would be unaware of the alleged substandard, non-compliant conditions pervading their company's manufacturing and quality control divisions – the heart of a company whose main business is manufacturing pharmaceuticals for public consumption. The idea that the defendants here would be unaware of these manufacturing and quality control problems is even more unlikely given the repeated Form 483s and the Warning Letter from the FDA. Form 483s are intended according to Plaintiffs, to inform "top management" of "significant objectionable conditions" according to Plaintiffs. FAC ¶ 44. Just as FAA warnings and failed inspections were considered so critical to the airline in *America West* such that outside directors were presumed to be aware, so to are FDA warnings and failed inspections crucial to a pharmaceutical company. An inference of scienter is strengthened by the allegation of pervasive and long standing problems which allegedly were covered up as a matter of policy at Impax.

Therefore, given the importance of manufacturing and quality control to the success of Impax and the fact that both areas of operation had been flagged by the FDA, it is a logical, and strong, inference that the defendants were aware of the alleged severe and pervasive problems in Impax's Hayward facility.

Accordingly, the Court concludes for purposes of the motion to dismiss Plaintiffs have sufficiently alleged a strong inference of scienter.

This order disposes of Docket No. 66.

IT IS SO ORDERED.

Dated: April 18, 2014

EDWARD M. CHEN
United States District Judge